



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,888	01/04/2007	Rolando Pajon Feyt	976-33 PCT/US	5857

23869 7590 11/17/2009
HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

EXAMINER

OGUNBIYI, OLUWATOSIN A

ART UNIT	PAPER NUMBER
----------	--------------

1645

MAIL DATE	DELIVERY MODE
-----------	---------------

11/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,888	Applicant(s) FEYT ET AL.	
	Examiner OLUWATOSIN OGUNBIYI	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/17/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

RESPONSE TO AMENDMENT

The amendment filed 7/13/09 has been entered into the record. Claims 1-36 have been cancelled. Claims 47-57 are pending and are under examination.

Information Disclosure Statement

The information disclosure statement filed 7/17/09 has been considered and an initialed copy is enclosed.

Specification

The objection to the specification is withdrawn in view of the amendment to remove embedded hyperlinks.

Rejections Withdrawn

The rejection of claims 32, 35-38, 40, 43-45 and 48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.

The rejection of claim 47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claim.

The rejection of claims 32, 35, 36, 40, 43-45 under 35 U.S.C. 102(b) as being anticipated by Fraser et al. WO 99/57280, November 1999 is withdrawn in view of the cancellation of the claims.

Art Unit: 1645

The rejection of claims 32, 35, 36-38, 40, 43-45 under 35 U.S.C. 103 as being unpatentable over Fraser et al. WO 99/57280, November 1999 in view of Tai et al (WO 97/28273) Aug. 1997 is withdrawn in view of the cancellation of the claims.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of claims 47 (newly applied to claim 47 in view of the amendment to the claim), 48 and new claims 49, 50 and 53-56 under 35 U.S.C. 102(b) as being anticipated by Fraser et al. WO 99/57280, November 1999 is maintained.

Amended claim 47 is now drawn to a method of inducing an immune response against an infection caused by bacteria from a *Neisseria meningitidis* or *Neisseria gonorrhoeae* in a human in need thereof comprising administering to the human an effective amount of a recombinant protein having the amino acid sequence consisting of SEQ ID NO: 4.

Amended claim 48 is drawn to a method of inducing an immune response against an infection caused by bacteria from a *Neisseria meningitidis* or *Neisseria gonorrhoeae* in a human in need thereof comprising administering to the human an effective amount of a pharmaceutical

Art Unit: 1645

composition comprising a recombinant protein and a pharmaceutical acceptable carrier, wherein the protein has the amino acid sequence consisting of SEQ ID NO: 4.

Fraser teaches a method of treating an infection due to *Neisseria* bacteria (p. 7 4th full paragraph) in a human (p. 34 2nd full paragraph) by administering to said human an effective amount (p. 36 2nd full paragraph) of immunogenic compositions comprising a protein having or has ("having" or "has" interpreted as comprising) the amino acid sequence consisting of SEQ ID NO: 4, thus inducing an immune response to said *Neisseria* bacteria (See p. 32 last paragraph, p. 34 under vaccines). See sequence alignment (provided in previous office action dated 10/31/07) and SEQ ID NO: 1522 on p. 798 of Fraser et al.

Fraser et al teaches said method wherein the bacteria are *Neisseria meningitidis* and wherein the bacteria are *Neisseria gonorrhoeae*. Fraser et al teaches said method comprising administering pharmaceutical compositions of said protein and a pharmaceutically acceptable carrier (p. 34 see under vaccines) wherein said pharmaceutical composition further comprises a polysaccharide antigen (p. 33 4th full paragraph); wherein said composition further comprises inactivated virus particles (inactivated microorganism, p. 33 4th full paragraph); wherein in said pharmaceutical composition further comprises a peptide antigen (p. 35 last paragraph); wherein in said pharmaceutical composition further comprises macrophage colony stimulating factor (growth factor, p. 35 2nd full paragraph); wherein said pharmaceutical composition is administered parenterally (p. 36 2nd to the last paragraph) and wherein said pharmaceutical composition is administered mucosally (via oral route, p. 36 2nd to the last paragraph).

Applicants' arguments:

Art Unit: 1645

Applicants respectfully disagree. Applicants note that claim 47 was not rejected under 35 U.S.C. § 102(b) in view of Fraser. Merely in order to expedite prosecution, however, applicants have canceled claims 32, 35, 36, 40, 43-45. Fraser fails to teach or disclose a protein having the sequence consisting of SEQ ID NO: 4. Claim 48 has been amended to read a protein having "the amino acid sequence consisting of SEQ ID NO: 4." New claims 49-57 also read on the protein having "the amino acid sequence consisting of SEQ ID NO: 4."

Response:

Applicants' arguments are carefully considered but are not persuasive. Claim 47 was not rejected under 35 U.S.C. § 102(b) in view of Fraser et al because the claim recited "...a recombinant protein encoded by an amino acid sequence consisting of SEQ ID NO: 4". Fraser et al did not teach the instant method comprising administering "...a recombinant protein encoded by an amino acid sequence consisting of SEQ ID NO: 4". The scope of the claim 47 was not clear and was rejected under 35 U.S.C. § 112 2nd paragraph because proteins are not encoded by proteins. However, Fraser et al is anticipatory reference to amended claim 47 and the other claims as set forth in the rejection above. The recombinant protein of Fraser et al has (comprises) the amino acid sequence consisting of SEQ ID NO: 4.

Instead of reciting that the "recombinant protein has/having the amino acid sequence consisting of SEQ ID NO: 4", Applicant may obviate the rejection by reciting that the "recombinant protein consists of the amino acid sequence set forth in SEQ ID NO: 4", provided

Art Unit: 1645

there is support for such an amendment. The rejection is maintained because “has/having” is interpreted as “comprises or comprising”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1645

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. The rejection of claims 47 (now amended), 48 and new claims 49-56 under 35 U.S.C. 103 as being unpatentable over Fraser et al. WO 99/57280, November 1999 in view of Tai et al (WO 97/28273) Aug. 1997 is maintained.

Amended claim 47 is now drawn to a method of inducing an immune response against an infection caused by bacteria from a *Neisseria meningitidis* or *Neisseria gonorrhoeae* in a human in need thereof comprising administering to the human an effective amount of a recombinant protein having the amino acid sequence consisting of SEQ ID NO: 4.

Amended claim 48 is drawn to a method of inducing an immune response against an infection caused by bacteria from a *Neisseria meningitidis* or *Neisseria gonorrhoeae* in a human in need thereof comprising administering to the human an effective amount of a pharmaceutical composition comprising a recombinant protein and a pharmaceutical acceptable carrier, wherein the protein has the amino acid sequence consisting of SEQ ID NO: 4.

Fraser teaches a method of treating an infection due to *Neisseria* bacteria such (p. 7 4th full paragraph) in a human (p. 34 2nd full paragraph) by administering to said human an effective amount (p. 36 2nd full paragraph) of immunogenic compositions comprising a protein comprising an amino acid sequence that is 100% identical to SEQ ID NO: 4, thus inducing an immune response to said *Neisseria* bacteria (see p. 32 last paragraph, p. 34 under vaccines). See sequence alignment (provided in previous office action dated 10/31/07) and SEQ ID NO: 1522 on p. 798 of Fraser et al.

Art Unit: 1645

Fraser et al teaches said method wherein the bacteria are *Neisseria meningitidis* and wherein the bacteria are *Neisseria gonorrhoeae*. Fraser et al teaches said method comprising administering pharmaceutical compositions of said protein and a pharmaceutically acceptable carrier (p. 34 see under vaccines) wherein said pharmaceutical composition further comprises a polysaccharide antigen (p. 33 4th full paragraph); wherein said composition further comprises inactivated virus particles (inactivated microorganism, p. 33 4th full paragraph); wherein in said pharmaceutical composition further comprises a peptide antigen (p. 35 last paragraph); wherein in said pharmaceutical composition further comprises macrophage colony stimulating factor (growth factor, p. 35 2nd full paragraph); wherein said pharmaceutical composition is administered parenterally (p. 36 2nd to the last paragraph) and wherein said pharmaceutical composition is administered mucosally (via oral route, p. 36 2nd to the last paragraph).

Fraser et al does not teach that the polysaccharide antigen is a capsular polysaccharide of *N. meningitidis* and does not teach that said pharmaceutical composition further comprises a bacterial polysaccharide-protein conjugate wherein said protein comprises an amino acid sequence set forth in SEQ ID NO: 4.

Tai et al teaches the use of a composition comprising *N. meningitidis* polysaccharide-*N. meningitidis* protein conjugate to induce an immune response against *Neisseria meningitidis* (See *N. meningitidis* group B polysaccharide conjugated to PorB protein of group B *meningitidis*, p. 32 lines 15-25). Tai et al teach that the T-cell independent quality of polysaccharide antigens in infants can be overcome by conjugating the polysaccharide to a protein carrier (p. 9 lines 8-10). Tai et al teaches the use of *N. meningitidis* proteins as carriers.

Art Unit: 1645

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to conjugate the protein of Fraser et al to a *N. meningitidis* capsular polysaccharide because Tai et al teaches the use of *N. meningitidis* proteins as carriers in order to overcome the T cell independent quality of polysaccharide antigens in infants.

As to claim 52, it would be prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to combine said composition of Fraser et al and said protein- polysaccharide conjugate because both compositions are used for inducing an immune response against *N. meningitidis* infection. It is prima facie obvious to combine two (or more) compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicants' arguments:

Applicants respectfully disagree. Applicants note that claim 47 was not rejected under 35 U.S.C. § 103(a) over Fraser and Tai.. Merely in order to expedite prosecution, however, applicants have canceled claims 32, 35, 36, 40, 43-45. Fraser fails to teach or disclose a protein having the sequence consisting of SEQ ID NO: 4. Claim 48 has been amended to read a protein having "the amino acid sequence consisting of SEQ ID NO: 4." New claims 49-57 also read on the protein having "the amino acid sequence consisting of SEQ ID NO: 4."

Response:

Art Unit: 1645

Applicants' arguments are carefully considered but are not persuasive. Claim 47 was not rejected under 35 U.S.C. § 102(b) in view of Fraser because the claim recited "...a recombinant protein encoded by an amino acid sequence consisting of SEQ ID NO: 4". Fraser et al did not teach the instant method comprising administering "...a recombinant protein encoded by an amino acid sequence consisting of SEQ ID NO: 4". The scope of the claim 47 was not clear and was rejected under 35 U.S.C. § 112 2nd paragraph because proteins are not encoded by proteins. However, Fraser et al is anticipatory reference to claim 47 now amended and to the other claims as set forth in the rejection above. The recombinant protein of Fraser et al has (comprises) the amino acid sequence consisting of SEQ ID NO: 4.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 52 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As to claim 52, the specification does not disclose a method of inducing an immune response against an infection caused by bacteria from a *Neisseria meningitidis* or *Neisseria*

Art Unit: 1645

gonorrhoeae in a human in need thereof comprising administering to the human an effective amount of a pharmaceutical composition comprising a recombinant protein and a pharmaceutical acceptable carrier, wherein the protein has the amino acid sequence consisting of SEQ ID NO: 4 wherein the pharmaceutical composition further comprises a bacterial polysaccharide-protein conjugate, wherein said protein consists of the amino acid sequence set forth in SEQ ID NO: 4. The specification does not teach a bacterial polysaccharide-protein conjugate, wherein said protein i.e. the protein of the conjugate consists of the amino acid sequence set forth in SEQ ID NO: 4. It is not clear whether Applicants are referring to the protein of the conjugate or the recombinant protein of claim 48 (see 35 U.S.C. 112, 2nd paragraph rejection below). In the case where, it is the protein of the conjugate that consists of the amino acid sequence set forth in SEQ ID NO: 4, Applicants may point to the specification for where support exists for claim 52. This is new matter.

As to claim 57, the specification does not disclose a method of inducing an immune response against an infection caused by bacteria from a *Neisseria meningitidis* or *Neisseria gonorrhoeae* in a human in need thereof comprising administering to the human an effective amount of a recombinant protein fusion protein, wherein the fusion protein comprises the N-terminus of p64K protein from *Neisseria meningitidis* and the amino acid sequence consisting of SEQ ID NO: 4.

Page 10 lines 1-3 teaches a cloning vector employed in the cloning and expression of protein NMB0928. Fig. 2 shows the cloning of gene NMB0928 into PM 100 cloning vector. Page 11 lines 9-12 is drawn to recognition of protein NMB0928 and a panel of un-related antigens by generated mAbs. Page 13-15 teaches cloning of NMB0928 and expression of the

Art Unit: 1645

protein and evaluation of the *immune response in mice*. None of these pages cited by Applicants for support for claim 57 which is drawn to:

“a method of inducing an immune response against an infection caused by bacteria from a *Neisseria meningitidis* or *Neisseria gonorrhoeae* in a human in need thereof comprising administering to the human an effective amount of a recombinant protein fusion protein, wherein the fusion protein comprises the N-terminus of p64K protein from *Neisseria meningitidis* and the amino acid sequence consisting of SEQ ID NO: 4”.

The method of inducing the immune response in mice is not the same as inducing an immune response in a human as claimed against an infection caused by bacteria from a *Neisseria meningitidis* or *Neisseria gonorrhoeae* as set forth in claim 57. This is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 52 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites “ further comprises a bacterial polysaccharide-protein conjugate, wherein said protein consists of the amino acid sequence set forth in SEQ ID NO: 4”. It is not clear in the claim whether the protein consisting of the amino acid sequence set forth in SEQ ID NO: 4 refers to the protein of the bacterial polysaccharide-protein conjugate or is a further

Art Unit: 1645

limitation of the recombinant protein of claim 48 which has (comprises) the amino acid sequence consisting of SEQ ID NO: 4.

An amendment to the claim clearly indicating that the protein consisting of the amino acid sequence set forth in SEQ ID NO: 4 is the protein of the conjugate (e.g. wherein the protein of said conjugate consists of SEQ ID NO: 4) or the is referring to the protein of claim 48, will obviate the rejection.

As to claim 57, the metes and bounds of "N-terminus of P64K protein from *Neisseria meningitidis*" is not clear. It is not clear in the claim what structure comprises said N-terminus of a P64K protein including where it starts and where it ends, how many acids as it is used in the claim. Applicant is requested to set forth in the claims what structure comprises "N-terminus of P64K protein from *Neisseria meningitidis*" provided there is original support for such in the specification as filed and would not constitute new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1645

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al. WO 99/57280, November 1999 in view of Cano et al. U.S. 6,146,635 Nov. 14, 2000 (cited in IDS).

The claim is drawn to a method of inducing an immune response against an infection caused by *Neisseria meningitidis* or *Neisseria gonorrhoeae* bacteria in a human in need thereof, comprising administering to the human an effective amount of a recombinant fusion protein, wherein the fusion protein comprises the N-terminus of P64k protein from *Neisseria meningitidis* and the amino acid sequence consisting of SEQ ID NO: 4.

Fraser teaches a method of treating an infection due to *Neisseria* bacteria such (p. 7 4th full paragraph) in a human (p. 34 2nd full paragraph) by administering to said human an effective amount (p. 36 2nd full paragraph) of immunogenic compositions comprising a protein comprising the amino acid sequence that consists of SEQ ID NO: 4, thus inducing an immune response to said *Neisseria* bacteria (see p. 32 last paragraph, p. 34 under vaccines). See sequence alignment (provided in previous office action dated 10/31/07) and SEQ ID NO: 1522 on p. 798 of Fraser et al. Fraser et al teaches said method wherein the bacteria are *Neisseria meningitidis* and wherein the bacteria are *Neisseria gonorrhoeae* (p. 7 3rd full paragraph).

Fraser et al does not teach said method using a fusion protein comprising the N-terminus of P64K protein from *Neisseria meningitidis* and the amino acid sequence consisting of SEQ ID NO: 4.

Art Unit: 1645

Cano et al teaches the use of a stabilizing sequence derived from the first 47 amino acids of the antigen P64K of *N. meningitidis* fused to protein. Due to said stabilizing sequence, the fusion protein is obtained in high amounts especially in a situation where commercial amounts of protein is need for the preparation of vaccines intended for human use. Cano et al teaches how to clone said first 47 amino acids of the antigen P64K of *N. meningitidis* fused to protein in a plasmid along with a protein of interest for expression in *E.coli*. See whole of Cano et al especially the abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to fuse the first 47 amino acids of the antigen P64K of *N. meningitidis* to the protein of Fraser et al, thus resulting in a recombinant fusion protein comprising (i.e. can include other amino acids) the N-terminus of P64K protein from *N. meningitidis* and the amino acid sequence consisting of SEQ ID NO: 4 as taught by Cano et al, with a reasonable expectation of success. The reason to do so is because the first 47 amino acids of the antigen P64K of *N. meningitidis* acts as a stabilizing sequence and the fusion protein can be obtained in high amounts especially in a situation where commercial amounts of protein are need for the preparation of vaccines intended for human use. See Cano et al, abstract.

Status of Claims

Claims 47-57 are rejected. No claims allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

Art Unit: 1645

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645